PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RLL-275WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB 03/02962	International filing date *(day/month/year)* 24.07.2003	Priority date *(day/month/year)* 25.07.2002
International Patent Classification (IPC) or both national classification and IPC A61K9/20		
Applicant RANBAXY LABORATORIES LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24.02.2004	09.08.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Epskamp, S Telephone No. +31 70 340-2857

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/02962

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-11 as originally filed

Claims, Numbers

1-54 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 39-43 with respect to industrial applicability

   because:

   ☒ the said international application, or the said claims Nos. 39-43 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-5, 9, 10, 12, 20, 27-30, 34-43, 45-48, 50, 52, 53
	No:	Claims	1, 6-8, 11, 13-19, 21-26, 31-33, 44, 49, 51 and 54
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-54
Industrial applicability (IA)	Yes:	Claims	1-38, 44-54
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 39-43 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents are referred to:

D1: Provigil® (modafinil) Tablets - FDA approved Draft Labeling, Cephalon, 1998
D2: FR 2 702 968 A
D3: WO 02/30414 A

I - Novelty

The present application does not meet the requirements of Article 33(2) PCT, because the subject-matter of claims 1, 6-8, 11, 13-19, 21-26, 31-33, 44, 49, 51 and 54 is not new.

1 - Document D1 discloses Provigol® modafinil tablets and the inactive ingredients therein (page 1: "Description"). Of these excipients, magnesium stearate and lactose are considered to be surface active agents (for lactose, compare "sucrose", listed in the application on page 6, line 14 as non-ionic surfactant). Thus the subject-matter of claims 1, 6-8, 11, 17-19, 22-26, 31-33, 44, 49, 51 and 54 lacks novelty over D1.

2 - Document D2 discloses modafinil microparticles comprising Tween 80 and optionally lactose or mannitol as surface active agents (examples 16 and 17, see also page 15, line 1 - page 16, line 7). Thus claims 1, 6-8, 11, 15, 16, 21, 24, 25, 44, 49, 51 and 54 are not new with respect to D2.

3 - Document D3 discloses self-emulsifying drug delivery systems comprising modafinil and surfactants (page 3, lines 1-28; examples). Claims 1, 7, 11, 13-15, 22, 24, 25, 44, 49, 51 and 54 therefore lack novelty over D3.

4 - Claims 2-5, 9, 10, 12, 20, 27-30, 34-43, 45-48, 50, 52 and 53 are new.

III - Inventive Step

1 - Lacking novelty, claims 1, 6-8, 11, 13-19, 21-26, 31-33, 44, 49, 51 and 54 cannot be considered inventive (Article 33(3) PCT).

2 - Regarding independent claim 39, D1 (see above) is considered the closest state of the art. D1 discloses that Provigil is indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy (page 10: "Indications and Usage").

Claim 39 differs from D1 in that the used dosage form comprises coarse and fine modafinil particles, wherein the fine modafinil particles have diameters less that 220 µm.

The size of the coarse particles is not defined, nor can any clear distinction be made between the coarse and the fine particles (even in the description the coarse and fine particles are only separated by a single point value (220 µm, see page 5, lines 22-24), so that the scope of the claims also includes normally distributed particle populations where there is no clear distinction between coarse and fine particles). Such a normally distributed particle population would not be expected to solve the problems relating to flow-properties, and thus no (unexpected) technical effect could be ascribed to the definition of this specific particle size.

As part of the invention does not appear to solve the problem of the invention, no inventive step can be acknowledged for the subject-matter of claim 39.

3 - The incorporation of the additional features contained in dependent claims 2-5, 9, 10, 12, 20, 27-30, 34-38, 40-43, 45-48, 50, 52 and 53 into the corresponding independent claim does not result in subject-matter which would be considered as involving an inventive step, because said features are not described as being related to a particular technical effect and, therefore, represent only trivial modifications.

III - Industrial Applicability

Claims 1-38 and 44-54 are considered to comply with Article 33(4) PCT (see also Item III above).